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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/567,534	08/17/2006	Daniel Deakter		8587

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EXAMINER	
PORTER, RACHEL L	
ART UNIT	PAPER NUMBER
3626	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/567,534	DEAKTER, DANIEL	
	Examiner	Art Unit	
	RACHEL L. PORTER	3626	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *06 February 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-10* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-10* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. This communication is in response to the application filed 2/6/06. Claims 1-10 are pending.

Claim Rejections - 35 USC § 101

2. 35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 8-10 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter.

Based on Supreme Court precedent and recent Federal Circuit decisions, the Office's guidance to examiners is that a §101 process must (1) be tied to a particular machine or apparatus or (2) transform underlying subject matter (such as an article or materials) to a different state or thing. *Diamond v. Diehr,* 450 U.S. 175, 184 (1981); *Parker* v. *Flook,* 437 U.S. 584, 588 n.9 (1978); *Gottschalk v. Benson,* 409 U.S. *63,* 70 (1972); *Cochrane* v. *Deener,* 94 U.S. 780,787-88 (1876). If neither of these requirements is met by the claim, the method is not a patent eligible process under §101 and should be rejected as being directed to nonstatutory subject matter.

There are two corollaries to the machine-or-transformation test. First, a mere field-of-use limitation is generally insufficient to render an otherwise ineligible method claim patent- eligible. This means the machine or transformation must

impose meaningful limits on the method claim's scope to pass the test. Second, insignificant extra-solution activity will not transform an unpatentable principle into a patentable process. This means reciting a specific machine or a particular transformation of a specific article in an insignificant step, such a data gathering or outputting, is not sufficient to pass the test.

While claim 8 recites "a computerized method" in the preamble, this is considered to be a field-of-use limitation, and does not make the claim patent-eligible. Claims 9-10 contain similar deficiencies and fail to correct the deficiencies of claim 8, and are therefore also rejected.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 1-10 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 recites the limitation "periodically match compatible patients and clinical studies *without reliance on calculation of probability based inferences of matching."* The Examiner understand that negative limitations are not inherently vague and indefinite. However, in the instant case, it is not what is being excluded by the negative limitation, without reliance on calculation on probability. Applicant has failed to define or clarify how the inventive matching algorithm or technique is performed. The proper scope of

applicant's invention cannot be properly ascertained and a potential infringer would not be advised of the metes and bounds of applicant's invention.

A similar analysis may be applied to claim 8, which recites a similar limitation. Claims 2-7 and 9-10 inherit the deficiencies of their respective independent claims through dependency and are therefore also rejected.

Claim Rejections - 35 USC § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

6. Claims 1-10 are rejected under 35 U.S.C. 102(e) as being anticipated by Rao et al US 20030130871 A1 (which incorporates by reference in its entirety US 2003/0120458A1, also by Rao et al.--portions from this application are cited in the rejection below as mentioned)

[claim 1] Rao discloses a system for automatically matching patients to clinical trials comprising:

- a database component operative to maintain: one or more hospital patient database components and their one or more hospital databases and their corresponding plurality of patient names and their medical records, (Figures 2-3-

(250 or 350) collects info. from hospitals); par. 17, 31) wherein said hospital patient database components are in communication with one or more medical practice database components and their corresponding plurality of specialties and their corresponding plurality of patient names and their medical records; (par. 17, 31, par 51—the Database/repository which receives hospital record data serves as a place where drug companies can go and requests list of people fitting desired criteria; system may also track physician for patients meeting particular criteria)

- a clinical studies database component and its corresponding plurality of clinical studies; (Figure 3, (390) studies database)
- a communications component to receive changes to said database component; and (par. 28-29 network interface; external storage using a database management system managed by the processor)
- a processor programmed to: periodically match compatible patients and clinical studies without reliance on calculation of probability based inferences of matching, (par. 48-50—questionnaires are used) and generate reports to matched medical practices in said medical practice database component having one or more patients matched to at least one clinical study. (par. 35 and 48-51)

[claim 2] Rao discloses the system according to claim 1, wherein: said database component identifies patient names associated with each medical practice in said medical practice database component; (par. 31, 34,-35) and said processor generates

reports to medical practices having identified patients, said reports including a listing of prospective patients for at least one clinical trial. (par. 36)

[claim 3] Rao discloses the system according to claim 1, further comprising: a searching component for searching said clinical studies database component, and said one or more hospital patient database components, wherein said communications component is adaptable to receive searching order instructions. (par. 51—clinical trials brokerage component can access CPR with patient hospital records; and can also have contact with patients seeking a particular study)

[claim 4] Rao discloses a he system according to claim 3, wherein: said processor is programmed with a rule-based system to vary search parameter priority, wherein said search parameter priority is set to search free text keywords or a phrase in a specified order. (par. 37--through incorporation by reference of “Patient data Mining," US 2003/013087; --Rao discloses that the CPR is generated by systematic search and extraction of free text par. 11-12)

[claim 5] Rao discloses the system according to claim 4, wherein: said search parameter priority is set to search free text keywords or a phrase last. (par. 37--through incorporation by reference of “Patient data Mining," US 2003/013087—par. 43: search and extraction from a text source may be carried out by phrase spotting, which requires a list of rules that specify the phrases of interest)

[claim 6] Rao disclose the system according to claim 1 wherein said processor is further programmed to convert database information from incompatible operating systems to the operating system of the processor. (par. 37--through incorporation by reference of “Patient data Mining," US 2003/01308 par. 44—Rao explains the generation of the CPR. The data sources include structured and unstructured information. Structured information may be converted into standardized units, where appropriate. Unstructured information may include ASCII text strings, image information in DICOM (Digital Imaging and Communication in Medicine) format, and text documents partitioned based on domain knowledge.)

[claim 7] Rao teaches the system according to claim 1, wherein said clinical studies database contains clinical trials selected from the group consisting of clinical drug trials and clinical device trials. (Figures 2-3; par. 31,50—clinical drug studies)

[claim 8] Rao discloses a computerized method for matching patients to clinical medical studies comprising:

- identifying a group of patients in a hospital database; (par. 36, 39)
- identifying at least one clinical study;(par. 50)
- maintaining a database identifying each said patient in said hospital database and each said clinical study; and (par. 51)
- comparing said group of patients in said hospital database to said clinical studies and matching one or more patients in a hospital database to one or more clinical

trials without reliance on calculation of probability- based inferences of matching. (Figure 4; par. 51-52)

[claim 9] Rao discloses the method according to claim 8, further comprising: maintaining said database to include a plurality of patient profiles associated with a corresponding medical practice;(par. 34-35) and notifying a medical practice when at least one of said patient profiles matches the requirements of said clinical studies. (par. 35)

[claim 10] Rao discloses the method according to claim 8, wherein said step of maintaining a database further comprises converting data from an incompatible operating system to the operating system of the processor. (par. 37--through incorporation by reference of “Patient data Mining," US 2003/01308 par. 44—Rao explains the generation of the CPR. The data sources include structured and unstructured information. Structured information may be converted into standardized units, where appropriate. Unstructured information may include ASCII text strings, image information in DICOM (Digital Imaging and Communication in Medicine) format, and text documents partitioned based on domain knowledge.)

Conclusion

7. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure:

- Tiles et al (US 20090150187A1)—a system for facilitating participation of subjects in clinical trials.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to RACHEL L. PORTER whose telephone number is (571)272-6775. The examiner can normally be reached on M-F, 9:30-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, (Christopher) Luke Gilligan can be reached on (571) 272-6770. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Rachel L. Porter/
Examiner, Art Unit 3626